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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,889	11/24/2003	Richard L. Mueller JR.	ACU-130	5151

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/720,889

Applicant(s)

MUELLER ET AL.

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 7, 8, 10, 11, 28, 31, 32, 33, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Raiken (US 5073169). Regarding claims 1 and 28, Raiken discloses a support comprising a spacer 12 having an aperture 14 to accommodate insertion of a catheter and a distal end 16 for contacting the breast (Col. 3, lines 5-12). See Fig. 1. Raiken further discloses an anchor 30 operably engagable at the proximal end of the spacer with a catheter received therein that is removably engagable with the breast (Col. 3, lines 52-65). See Fig. 3.
3. Regarding claim 2, Raiken discloses that the spacer 12 is made of an elastomeric material (Col. 2, line 30).
4. Regarding claims 6 and 31, Raiken discloses that the spacer 10 has an adhesive layer 22 on the undersurface of the distal end 16 (Col. 3, lines 11-12).

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5. Regarding claims 7, 8, 32 and 33, Raiken discloses that the anchor 30 is removably engagable with the catheter by way of being secured around its periphery (Col. 3, lines 57-59) thereby defining the aperture through which the catheter is received.

6. Regarding claims 10 and 35, Raiken discloses that the spacer and the anchor are integral (Col. 57-58).

7. Regarding claims 11 and 36, the spacer disclosed by Raiken inherently receives the intermediate portion of the catheter since one end is inserted into the patient and the other end is operable with the surgical implements with which it is being used (Col. 3, lines 59-60).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Kriesel (US 5743879). Claim 3 differs from Raiken in calling for the spacer to be a plug of a compressible elastomer. Kriesel discloses a spacer means made of a compressible elastomeric plug (Col. 11, lines 33-35). Kriesel further discloses that this elastomeric spacer plug provides a force and returns to its starting configuration after deformation (Abs, lines 4-11). Therefore, it

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would have been obvious to one of ordinary skill in the art at the time of invention to modify the spacer disclosed by Raiken to be of a compressible elastomeric material as taught by Kriesel so that it would provide a force and resist deformation.

10. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Kriesel as applied to claim 3 above, and further in view of Cesarczyk et al (US 6165156). Claim 4 differs from the teachings of Raiken in view of Kriesel in calling for the compressible elastomer to be polyurethane foam. Cesarczyk discloses a device for securing a catheter to a patient comprising a flexible spacer layer 12 made of polyurethane foam or another suitable material (Col. 3, lines 55-59). Cesarczyk further discloses that this layer promotes proper cannula angle and provides additional patient comfort due to the resilience of the material (Col. 2, lines 58-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the spacer taught by Raiken in view of Kriesel of polyurethane foam to promote proper insertion angle and provide patient comfort.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Kriesel as applied to claim 3 above, and further in view of Marshall et al (US 4516968). Claim 5 differs from the teachings of Raiken in view of Kriesel in calling for the spacer to define a slit for receiving the catheter. Marshall discloses a device for retaining a catheter comprising a spacer 10 with a radial slit 22 through which the body of the catheter 24 is passed until it is in place in the catheter hole 16 in the spacer 10 (Col. 2, lines 48-51). See Fig. 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the spacer of

the catheter retainer taught by Raiken in view of Kriesel to have a slit as taught by Marshall so that the spacer can be slid into place.

12. Claims 9 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Bierman (US 5855591). Claim 9 differs from Raiken in calling for the anchor to include an adhesive for removably securing it to the breast. Bierman discloses a catheter securement device comprising an anchor with an adhesive bottom surface to be removably secured to the patient's skin (Col. 2, lines 2-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the anchor disclosed by Raiken to include an adhesive layer as taught by Bierman so that it could be removably attached to the patient's skin.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Taylor (US 3584770). Claim 29 differs from the teachings of Raiken in calling for the spacer to be a cylindrical plug of compressible elastomer. Taylor discloses a cylindrical rubber plug 28 utilized to receive and secure a cannula 30 (Col. 2, lines 25-30). See Fig. 3. Furthermore, it is well known in the art that rubber stoppers are available in a variety of shapes and sizes to secure tubes of all types in a specific orientation and location. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the spacer disclosed by Raiken of a cylindrical plug of compressible elastomer as taught by Taylor so that it can secure the catheter in the desired position.

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14. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Taylor as applied to claim 29 above, and further in view of Marshall. As discussed regarding claim 5 above, Marshall discloses a spacer 10 with a radial slit 22 through which the body of the catheter 24 is passed until it is in place in the catheter hole 16 in the spacer 10 (Col. 2, lines 48-51). See Fig. 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the spacer of the catheter retainer taught by Raiken in view of Taylor to have a slit as taught by Marshall so that the spacer can be slid into place.

15. Claims 12, 15, 16, 17, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire et al (US 6607502). Claim 12 differs from Raiken in calling for the spacer and anchor, capable of substantially maintaining a predetermined position of a catheter in the mammary duct, to be contained within in a kit further including a catheter. Claim 15, depending from claim 12 calls for the spacer to include an adhesive for removably securing it to the breast, a feature included in the disclosure of Raiken as discussed with regard to claim 6. Claim 16, also depending from claim 12, calls for the anchor to be removably engaged with the catheter, also a feature disclosed by Raiken as discussed with regard to claims 7 and 32. Claim 17, depending from claims 16 and 12, calls for the anchor to define an aperture through which the catheter can extend, another feature disclosed by Raiken as discussed with regard to claims 8 and 33. Claim 26, depending from claim 12, calls for the anchor and the spacer to be integral, which is disclosed by Raiken. Claim 27, depending from claim 12, calls for the spacer to receive the intermediate portion of the catheter, which is a feature of the device disclosed by Raiken. Maguire discloses a kit containing multiple catheters of different sizes

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from which a treating physician may choose a particular device to meet the particular needs of a particular patient (Col. 27, lines 39-44). It is also well known in the art that since medical devices such as the one herein disclosed need to be sterile, it is obvious to contain them in a kit that is capable of maintaining the sterilization of all components of the device until the time of use. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to contain the catheter retainer disclosed by Raiken in a kit with catheters as taught by Maguire so that the treating physician may choose the particular device to meet the specific needs of the patient and so that all components remain sterile before use.

16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire as applied to claim 12 above, and further in view of Taylor. Claim 13 differs from the teachings of Raiken in view of Maguire in calling for the spacer to be a substantially cylindrical plug of compressible elastomer. As discussed with regard to claim 29 above, Taylor discloses a cylindrical rubber plug 28 utilized to receive and secure a cannula 30 (Col. 2, lines 25-30). See Fig. 3. Furthermore, it is well known in the art that rubber stoppers are available in a variety of shapes and sizes to secure tubes of all types in a specific orientation and location. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to form the spacer disclosed by Raiken of a cylindrical plug of compressible elastomer as taught by Taylor so that it can secure the catheter in the desired position.

17. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire in further view of Taylor as applied to claim 13 above, and further in view of Marshall

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et al. Claim 14 differs from the teachings mentioned in calling for the spacer to define a slit for receiving an intermediary portion of the catheter. Marshall discloses, as discussed regarding claim 5, a device for retaining a catheter comprising a spacer 10 with a radial slit 22 through which the body of the catheter 24 is passed (Col. 2, lines 48-51). See Fig. 7. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the spacer of the catheter retainer taught by Raiken in view of Maguire to have a slit as taught by Marshall so that the spacer can be slid into place.

18. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire as applied to claim 12 above, and further in view of Bierman. Claim 18 differs from the teachings of Raiken in view of Maguire in calling for the anchor to include an adhesive layer. As discussed regarding claims 9 and 34, Bierman discloses a catheter securement device comprising an anchor with an adhesive bottom surface to be removably secured to the patient's skin (Col. 2, lines 2-3). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the kit disclosed by Raiken in view of Maguire to include a spacer with an adhesive layer as taught by Bierman so that it could be removably attached to the patient's skin.

19. Claims 19, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire as applied to claim 12 above, and further in view of Sheridan (US 3612050). Claim 19 differs from Raiken in view of Maguire in calling for the catheter to include a hub. Claim 20, depending from claim 19 calls for the hub to define a through passage in fluid

communication with the catheter. Claim 21, also depending from claim 19 calls for the through passage to terminate as a luer taper. Sheridan discloses a catheter 48 with a hub 54 in fluid communication with the catheter terminating at a luer taper 56 (col. 4, lines 11-17). See Fig. 6. Sheridan further discloses that this device has improved insertability (See Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include on the catheter disclosed by Raiken in view of Maguire a hub in fluid communication with the catheter terminating in a luer taper to improve insertability of the catheter.

20. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire as applied to claim 12 above, and further in view of Gullen (US 3890970). Claim 22 differs from the teachings of Raiken in view of Maguire in calling for the catheter to include a stop member. Claim 23, depending from claim 22 calls for the stop member to be in the form of an annular detent. Gullen discloses a catheter 11 comprising an integral or fixed stop member in the form of a ring 16 to limit the depth of penetration to which the catheter can be inserted into the tissue (Col. 2, lines 67-68 – Col. 3, line 1). See Fig. 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the catheter disclosed by Raiken in view of Maguire to include an annular stop member as taught by Gullen to limit the insertion depth of the catheter.

21. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raiken in view of Maguire as applied to claim 12 above, and further in view of Cocker et al (US 2002/0193748). Claim 24 differs from Raiken in view of Maguire in calling for the spacer to be


a spring member. Claim 25, depending from claim 24, differs from Raiken in view of Maguire in calling for the spacer to be a leaf spring. Cocker discloses a safety needle with a spacer in the form of a leaf spring 120 that serves to bias the two adjacent parts away from each other (Col. 3, ¶ 50). See Figs. 1a-d. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention include in the kit disclosed by Raiken in view of Maguire a spacer in the form of a leaf spring so that the spacer could bias the members on either side of it.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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